Global Harmonization Task Force Study Groups 2 and 3

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Study Group 2: Mission

The purpose of a vigilance and postmarket surveillance system is to improve the protection of the health and safety of patients, users and others by reducing the likelihood of the same type of adverse incident being repeated in different places at different times. This is to be achieved by the evaluation of reported incidents, and where appropriate, dissemination of information which could be used to prevent such repetitions, or to alleviate the consequences of such repetitions.

SG2 Final Documents

- **SG2-N16: Charge & Mission Statement**
- **SG2-N6R2: Comparison of the Device Adverse Reporting Systems in USA, Europe, Canada, Australia & Japan**
- **SG2-N7R2: Minimum Data Set for Manufacturer Reports to Competent Authority**
- **SG2-N8R4: Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices**
- **SG2-N9R5: Global Medical Devices Vigilance Report**
- **SG2-N21R8: Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative**

SG2 Working Drafts and Proposed

Proposed -

- **SG2-N20R5: Competent Authority Reporting Criteria**
- **Sg2-N27: Terms & Definitions**

Working Draft -

- **SG2-N31R2: Proposal for Reporting of Use Errors with Medical Devices**

If implemented, SG2 recommendations would:

- **Harmonize the definition of what is and what is not a reportable event**
  - **In that way, any manufacturer would have one algorithm for making decisions about whether or not to report**

Two examples:

- **Well known and foreseeable side effects will be exempt from reporting, if clearly documented in master technical file**
  - **For certain products, this could reduce reporting significantly**
  - **Finding a universal definition of side effect**
- **Clinical determination that device was not involved can reduce reporting**
  - **Already in place for MDR - reports still arrive**

Current concern:

- **Whether to have mandatory reporting of use errors to Competent Authority**
  - **Some countries already have such a requirement**
  - **Industry concern about reporting on their "customers"**
  - **Use error recognized as important and persuasive - disagreement how to resolve**

SG3: General Direction

Reviewing the Good Manufacturing Practice (GMP) requirements and methodologies used by national regulatory bodies, evaluate existing quality design systems and develop guidance documents; develop guidance in the area of design control and process validation

SG3: Final Documents

- **SG3-gqualitysys: Guidance on Quality Systems for the Design & Manufacturing of Medical Devices**
- **SG3-descontrolguid: Design Control Guidance for Medical Device Manufacturers**
- **SG3-processval: Process Validation Guidance for Medical Device Manufacturers**

SG3: Working Draft

- SG3-N99-5RSG3 Comments & Recommendations on ISO/DIS 9001:2000, ISO/DIS 9000:2000 & the Revisions to ISO 13485 & ISO 13488

If implemented SG3 recommendations would:

- **Provide for a consistent interpretation of quality system requirements**
  - **Use of guidance documents on design control and process validation are keys**
  - **Competent Authorities (and Notified Bodies) will expect an understanding of these guidance documents**
  - **Documents useful for educational purposes**

Current concern:

- **ISO9001:2000**
  - **Deharmonizing because some proposed requirements at the DIS contain requirements for "customer satisfaction" and requirement on efficiency for the quality management system**
  - **SG3 goal to require minimum necessary to protect public health**
  - **Moving backwards!**